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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/561,372

04/23/2007

Paul E. Young

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EXAMINER

MARTINELL, JAMES

ART UNIT

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1634

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/561,372	Applicant(s) YOUNG ET AL.	
	Examiner James Martinell	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 December 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) 17-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/23/09 and 9/11/09</u> . | 6) <input type="checkbox"/> Other: _____ |

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Applicants are correct that the wrong box was checked on form PTO-326 mailed November 19, 2009. Claims 1-32 should have been listed under Box No. 8 as subject to a restriction requirement rather than under Box No. 7 as being objected to. The error is regretted.

Applicant's election of Group 1, claims 1-16 in the reply filed on December 3, 2009 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 17-32 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on December 3, 2009.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are vague and indefinite.

- (a) The recitation of "similar change" (claim 1) is vague and indefinite because it is not clear how dissimilar the change must be to be excluded from the claim. Thus, the metes and bounds of the claims are not clear.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3-8, and 16 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Natsoulis (U.S. Patent Application Publication 2003/0180808). Natsoulis teaches a method for generating a group of compounds having related activities and comprising the steps of determining a change in expression profiles of a set of selected genes. For example, providing a selected drugs, contacting each with a subject cell, measuring the expression responses (*e.g.*, paragraphs 0008, 0015-0018, and 0035 and claims 1, 11, and 12), and comparing changes of expression profiles. Natsoulis also discloses

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determining a change of expression profiles in the presence and absence of a first and second compound (*e.g.*, paragraphs 0008, 0015-0018, 0035, claim 1, and Figure 3). Natsoulis also discloses genes present in a cell and are part of a genome (*e.g.*, paragraph 0120) and thus anticipates claims 3 and 16. The reference further discloses measurement of transcription and changes in cell physiology. The reference also discloses therapeutic activity of compounds (*e.g.*, paragraph 0033).

Claims 1, 3-8 and 14-16 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Bristow et al (WO 03/023066 (March 20, 2003)) (Bristow et al I). Bristow et al I discloses a method of identifying genes involved in disease by comparing gene expression profiles from subjects treated differently (*e.g.*, page 3, lines 5-29 and Example 1 on pages 45-46). The reference also discloses antineoplastic activity and measurement of gene expression by examining profiles of transcription and synthesis of RNAs. Bristow et al I also discloses changes in cell physiology (page 5, lines 1-22) and therapeutically active compounds (*e.g.*, pages 34-43).

Claims 1, 3-8 and 14-16 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Bristow et al (U.S. Patent Application Publication 2003/0096782) (Bristow et al II). Bristow et al II discloses a method of identifying genes involved in disease by comparing gene expression profiles from subjects treated differently (*e.g.*, paragraphs 0011 and 0240-0244). The reference also discloses antineoplastic activity and measurement of gene expression by examining profiles of transcription and synthesis of RNAs. Bristow et al II also discloses changes in cell physiology (paragraphs 0015-0016) and therapeutically active compounds (*e.g.*, paragraphs 0149-0238).

Claims 2, 12, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over either one of Bristow et al (WO 03/023066 (March 20, 2003)) (Bristow et al I) or Bristow et al (U.S. Patent Application Publication 2003/0096782) (Bristow et al II) in view of Skolnick et al 5,624,819. The discussions of each of Bristow I and Bristow II in the previous two rejections are incorporated here. Skolnick et al teaches the desirability of screening for anticancer drugs (*e.g.*, column 3, line 60 through column 4, line 10). It would have been obvious for one of ordinary skill in the art at the time the invention was made to use the method of either one of Bristow et al I or Bristow et al II to screen for

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anticancer drugs effective against colon cancer as suggested by Skolnick et al for the purpose of treating cancers.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over either one of Bristow et al (WO 03/023066 (March 20, 2003)) (Bristow et al I) or Bristow et al (U.S. Patent Application Publication 2003/0096782) (Bristow et al II) in view of any one of Fujimori et al (U.S. Patent Application Publication 2002/0054865), Boothman et al (U.S. Patent No. 5,763,625), Zeldis et al (U.S. Patent Application Publication 2002/0035090), Romanczyk, Jr. et al (U.S. Patent Application Publication 2002/0049166), Ylihonko et al (U.S. Patent No. 6,399,583), or Hunter et al (U.S. Patent Application Publication 2002/0052404). The discussions of each of Bristow I and Bristow II in the rejections under 35 U.S.C. § 102 (a) and (e) hereinabove are incorporated here. Fujimori et al discloses camptothecine to be an antitumor agent (*e.g.*, paragraph 0169). Boothman et al discloses β -lapachone to be an antineoplastic agent (*e.g.*, see the Abstract). Zeldis et al teaches the each of suramin, doxorubicin hydrochloride, etoposide, epirubicin, and mitoxantrone is an anticancer agent (*e.g.*, see paragraph 0070). Romanczyk, Jr. et al discloses that m-AMSA is an antitumor compound (*e.g.*, paragraph 0174). Ylihonko et al discloses aclacinomycin from *Streptomyces galilaeus* to be an anticancer agent (*e.g.*, column 2, lines 39-62) and the Abstract). Hunter et al discloses that aurintricarboxylic acid is an anti-angiogenic agent. It would have been obvious for one of ordinary skill in the art at the time the invention was made to use the method of either one of Bristow et al I or Bristow et al II to screen for either anticancer agents or anti-angiogenic agents as disclosed in any one of the secondary references for the uses disclosed in any one of the secondary references.

Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over either one of Bristow et al (WO 03/023066 (March 20, 2003)) (Bristow et al I) or Bristow et al (U.S. Patent Application Publication 2003/0096782) (Bristow et al II) in view of Mobashery et al (U.S. Patent Application Publication 2002/0037916). The discussions of each of Bristow I and Bristow II in the rejections under 35 U.S.C. § 102 (a) and (e) hereinabove are incorporated here. Mobashery et al discloses topoisomerase II inhibitors to be antineoplastic agents (*e.g.*, see paragraph 0126). It would have been obvious for one

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of ordinary skill in the art at the time the invention was made to use the method of either one of Bristow et al I or Bristow et al II to screen for topoisomerase II inhibitors as disclosed in the secondary reference for the uses disclosed in the secondary reference.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James Martinell whose telephone number is (571) 272-0719.

The examiner works a flexible schedule and can be reached by phone and voice mail. Alternatively, a request for a return telephone call may be e-mailed to james.martinell@uspto.gov. Since e-mail communications may not be secure, it is suggested that information in such requests be limited to name, phone number, and the best time to return the call.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave T. Nguyen, can be reached on (571) 272-0731.

OFFICIAL FAX NUMBER

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300. Any Official Communication to the USPTO should be faxed to this number.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/James Martinell/
Primary Examiner
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